

# Media and Political Rhetoric vs. Real Science

## *Protecting DSHEA and Your Access to Dietary Supplements*

### Why Did Nutraceutical Challenge FDA's Action?

- We wanted to make sure FDA follows DSHEA (the Dietary Supplement Health and Education Act) and uses sound science to stop the sale of ingredients at dose levels that cause harm.
- We were concerned about a new concept — a “risk-benefit” test — that caused all supplements to be treated like drugs and gave FDA the power to ban any dietary supplement at its discretion.
- Dietary supplements should not be treated like drugs. Supplements are typically natural food products. Treating them like drugs — with pre-market approval and clinical studies required — would mean an end to consumer access to supplements.
- We believed our low-dose ephedra product was safe. It was not designed for weight loss, but for traditional uses, like respiratory support.

### Why Did FDA Ban Ephedra?

- Over eight years, FDA proposed, withdrew and re-proposed, limits on dietary supplements with ephedrine alkaloids. Until the final rule, all the proposed rules exempted low-dose ephedra products.
- During those eight years, FDA took few actions against manufacturers who sold high-dose ephedra. The result? Negative and often inaccurate publicity surrounding ephedra supplements.
- In the final rule, FDA announced a ban on *all* dietary supplements containing *any* ephedrine alkaloids, but did not ban them in foods like Chinese herbal tea.

### What Did the Court Decide?

- Under DSHEA, dietary supplements are to be regulated as foods.
- Like other foods, dietary supplements are “presumed to be safe.”
- FDA’s “risk-benefit” test is contrary to what Congress intended when it passed DSHEA in 1994.
- To ban a dietary supplement, FDA must establish that the specific dose recommended in the labeling presents a significant or unreasonable risk of illness or injury. FDA didn’t do that for low-dose ephedra. FDA can’t stop Nutraceutical and Solaray from selling their low-dose ephedra product.
- FDA has to rewrite its ephedra rule.

### How Does the Decision Affect Me?

- The Court’s ruling protects your access to dietary supplements. FDA can’t arbitrarily ban them.
- The ruling requires FDA to pay attention to dosage in determining if a supplement is dangerous.
- The ruling prohibits FDA from treating dietary supplements like drugs — it must treat them like foods, as DSHEA specifies.

### Does the Ruling Mean that Ephedra is Safe?

- Nutraceutical’s case only involved Solaray® Ephedra, a low-dose whole herb product.
- The court said FDA did not have adequate scientific evidence that low-dose ephedra is unsafe.
- Since low-dose ephedra is a food, it is presumed to be safe.
- The court did not analyze scientific evidence about the safety of ephedra products at higher doses.

### What’s Next for Ephedra?

- FDA must exempt low-dose ephedra at 10 mg or less of ephedrine alkaloids per day. FDA must reopen the rulemaking to establish the precise dose level above 10 mg ephedrine alkaloids at which ephedra presents a significant or unreasonable risk of illness or injury.
- FDA can also choose to appeal the court’s ruling.
- We are evaluating the reintroduction of Solaray® Ephedra. We want to do it in a way that is consistent with our obligations to our customers and in compliance with the law and the recent court decision.

### What Can I Do To Protect My Access To Supplements?

Let your Congressman and Senators know that access to supplements is important to you. A useful web site for contacting them is:

[www.saveoursupplements.org](http://www.saveoursupplements.org)

Contact Nutraceutical by email at:  
[savesupplements@nutracorp.com](mailto:savesupplements@nutracorp.com)

